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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,710	02/24/2004	Mark L. Nelson	PAZ-025CPCNRCE	3651

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EXAMINER	
FREISTEIN, ANDREW B	
ART UNIT	PAPER NUMBER
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,710	NELSON ET AL.	
	Examiner	Art Unit	
	Andrew B. Freistein	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-14,16,19,21,23,25,26,28-40,56-68,82 and 103-139* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-14,16,19,21,23,25,26,28-40,56-68,82 and 103-139* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/08/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This communication is in response to the Request for Continued Examination (RCE) filed on 10/31/2006.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under Ex Parte Quayle, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the feet set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission on 8/25/2006 has been considered and has been entered.

Claims 1-4, 6-14, 16, 19, 21, 23, 25, 26, 28-40, 56-68, 82 and 103-139 are pending. Claims 5, 15, 20, 22, 27, 41-55, 69-81 and 83-102 were cancelled.

Information Disclosure Statement

Applicant's information disclosure statement (IDS), filed on 06/08/2006, has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Copending Applications

Applicant must bring to the attention of the Examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CAFC 2003).

Applicant is kindly requested to show the relevancy of the claimed invention from the long list of copending applications and other references cited in the IDS to the Office.

Claim Rejections – Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

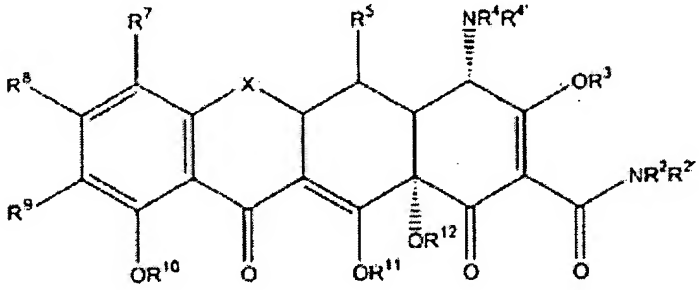
(Pending Rejection) Claims 1-10, 41-55, 69-76, and 82 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26, 32 and 51-81 of U.S. Pat. No. 6,818,634. As a result of the amendment to claims 1 and 82 and the cancellation of claims 41-55 and 69-76, the rejection is withdrawn.

(New Rejection) Claims 1-4, 6-14, 16, 19, 21, 23, 24, 30-40 and 82 are provisionally rejected on the ground of nonstatutory double patenting over claims 1 and

26-54 of copending Application No. 10/839,023. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

The instant application claims a compound and pharmaceutical composition comprising a compound of formula (I),



, wherein:

X is CHC(R^{13}Y'Y), $CR^{6'}R^6$, S, NR^6, or O;

R^2 is hydrogen, alkyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, arylalkyl, aryl, heterocyclic, heteroaromatic or a prodrug moiety;

R^4 and $R^{4'}$ are each hydrogen, alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, arylalkyl, aryl, heterocyclic, heteroaromatic or a prodrug moiety;

$R^{2'}$, R^3, R^{10}, R^{11} and R^{12} are each hydrogen or a pro-drug moiety;

R^5 is hydrogen, hydroxyl, or a prodrug moiety;

R^6, $R^{6'}$, and R^8 are each independently hydrogen, alkyl, alkenyl, alkynyl, aryl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, arylalkyl, or halogen;

R^7 is hydrogen, dialkylamino, ~~heteroaryl-amino,~~ or $NR^{7c}C(=W')WR^{7a}$;

R^8 is hydrogen;

R^{13} is hydrogen, hydroxy, alkyl; alkenyl; alkynyl; alkoxy; alkylthio; alkylsulfinyl; alkylsulfonyl; alkylamino; or an arylalkyl;

Y' and Y are each independently hydrogen; halogen; hydroxyl; cyano, sulfhydryl; amino; alkyl; alkenyl; alkynyl; alkoxy; alkylthio; alkylsulfinyl; alkylsulfonyl; alkylamino; or an arylalkyl;

R^9 is hydrogen~~,~~ or $NR^{9c}C(=Z')ZR^{9a}$~~, or heteroaryl amino~~;

Z is ~~$CR^{9d}R^{9e}$, NR^{9b}, or~~ O;

Z' is O or S;

R^{9a} is ~~, R^{9d}, and R^{9e} are each independently ethyl, t-butyl, n-butyl, i-butyl, or n-pentyl,~~ substituted alkyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, arylsulfonyl, alkoxycarbonyl, arylcarbonyl, alkylamino, arylalkyl, aryl, heterocyclic, heteroaromatic, a steroid, absent, or a prodrug moiety~~, and R^{9d} and R^{9e} may be linked to form a ring~~;

~~R^{9b} and~~ R^{9c} is ~~are each independently~~ hydrogen, alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, arylsulfonyl, alkoxycarbonyl, arylcarbonyl, alkylamino, arylalkyl, aryl, heterocyclic or heteroaromatic;

W is $CR^{7d}R^{7c}$, NR^{7b} or O;

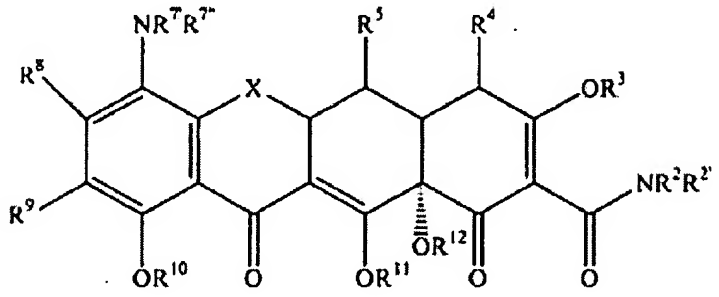
W' is O or S; and

R^{7a}, R^{7b}, R^{7c}, R^{7d}, and R^{7e} are each independently hydrogen, alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, arylsulfonyl, alkoxycarbonyl, arylcarbonyl, alkylamino, arylalkyl, aryl, heterocyclic, heteroaromatic, absent, or a prodrug moiety, and R^{7d} and R^{7e} may be linked to form a ring;

and pharmaceutically acceptable salts thereof, provided that at least one of R^9 is not hydrogen when R^7 is hydrogen or dialkylamino.

Determining the Scope and Content of the Copending Application

The copending application claims a compound and pharmaceutical composition comprising the compound of formula (I),



, wherein

X is $CHC(R^{13}Y'Y)$, or $CR^{6}R^{6'}$, ~~S, NR^{6}, or O~~;

R^2, $R^{4'}$, $R^{4''}$, $R^{7'}$ and $R^{7''}$ are each hydrogen, alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, arylalkyl, aryl, heterocyclic, heteroaromatic or a prodrug moiety;

R^4 is $NR^{4'}R^{4''}$, alkyl, alkenyl, alkynyl, aryl, hydroxyl, halogen, or hydrogen;

$R^{2'}$, R^3, R^{10}, R^{11} and R^{12} are each hydrogen or a pro-drug moiety;

R^5 is hydroxyl, hydrogen, thiol, alkanoyl, aroyl, alkaroyl, aryl, heteroaromatic, alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, arylalkyl, alkyl carbonyloxy, or aryl carbonyloxy;

R^6 and $R^{6'}$ are independently hydrogen, methylene, absent, hydroxyl, halogen, thiol, alkyl, alkenyl, alkynyl, aryl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, or an arylalkyl;

R^9 is nitro, alkyl, alkenyl, alkynyl, aryl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, arylalkyl, amino, arylalkenyl, arylalkynyl, thionitroso, or $-(CH_2)_{0-3}NR^{9c}C(=Z')ZR^{9a}$;

Z is $CR^{9d}R^{9e}$, S, NR^{9b} or O;

Z' is NR^{9f}, O or S;

R^{9a}, R^{9b}, R^{9c}, R^{9d}, R^{9e} and R^{9f} are each independently hydrogen, acyl, alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, arylalkyl, aryl, heterocyclic, heteroaromatic or a prodrug moiety;

R^8 is hydrogen, hydroxyl, halogen, thiol, alkyl, alkenyl, alkynyl, aryl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, or an arylalkyl;

R^{13} is hydrogen, hydroxy, alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, or an arylalkyl;

Y' and Y are each independently hydrogen, halogen, hydroxyl, cyano, sulfhydryl, amino, alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, or an arylalkyl, and pharmaceutically acceptable salts, esters and prodrugs thereof.

Ascertaining the Differences Between the Instant Application and the Prior Art

The instant application claims R^7 to be H, dialkylamino, or $NR^{7c}C(=W')WR^{7a}$; and claims R^9 to be H or $NR^{9c}C(=Z')ZR^{9a}$. The copending application claims R^7 to be $NR^{7'}R^{7''}$, wherein $R^{7'}$ and $R^{7''}$ are each alkyl and R^9 is claimed to be $-(CH_2)_{0-3}NR^{9c}C(=Z')ZR^{9a}$. Thus, the copending application contains the limitation of $NR^{7'}R^{7''}$ rather than R^7 alone and contains the limitation of in R^9 of $(CH_2)_{0-3}$

Finding Prima Facie Obviousness

The products claimed in the instant application are also claimed in the copending application. One of ordinary skill in the art would be motivated to produce the same compounds in the instant application with the copending application. Claims 26-54 of the copending application are all drawn to products wherein R^9 is $(CH_2)_{0-3}NR^{9c}C(=Z')ZR^{9a}$. Moreover, claims 36-50 all lead one of ordinary skill in the art to produce compounds wherein R^{9a} is substituted aryl. Similarly, instant claims 23, 24, and 30-40 each claim compounds wherein R^{9a} is substituted aryl. Therefore, one of ordinary skill in the art would be motivated to prepare similar compounds.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 103

Claims 1-5, 11-13, 16, 18-19 and 82 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barden et al, "'Glycylcyclines' 3. 9-Aminodoxycyclinecarboxamides," J. Med. Chem., 37(20), 3205-11 (1994). Claims 5 and 18 were cancelled. The rejection of claims 1-4, 11-13, 16, 19 and 82 is maintained.

The claims were amended to change R^{9a} from "ethyl" to "substituted alkyl." Claim 1 does not state what the substituent on the alkyl group is. According to the specification, examples of possible substituents are alkyl, alkenyl, halogen, hydroxyl, alkoxy, etc. (see p. 6, line 23 – p. 7, line 10). Thus, in the simplest case, the alkyl group can be substituted with an alkyl group. Consequently, R^{9a} is still drawn to an ethyl group.

To those skilled in the chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious, because one skilled in the art would have been motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used in pharmaceutical compositions. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Applicant points out that the reference shows limited activity of the tetracycline compounds until a nitrogen atom was incorporated into the 9-position side chain.

Consequently, Applicant contends, one skilled in the art would not have been motivated to prepare compounds in with R^{9a} is ethyl or unsubstituted alkyl.

Examiner respectfully disagrees with Applicant's analysis. The prior art teaches that the introduction of the nitrogen atom showed a "first hint of limited activity." Then, the reference points out that substitution of the amine with a methyl group "further increased the potency, a trend which continued as the size of the alkyl group increased" (p. 3206, col. 2, last paragraph). Thus, the reference shows that as more alkyl groups were added onto the amide chain, the greater the potency of the compound.

In the instant application, the amide chain is not present when R^{9a} is $NR^{9c}C(=Z')ZR^{9a}$; Z is O; Z' is O; and R^{9a} is substituted alkyl. Z' is O rather than NH. However, the reference makes no mention of increased potency with an alkoxy group; it only mentions a trend with the amide group. Nevertheless, because the potency increases with as the alkyl chain gets larger, one of ordinary skill in the art would be motivated to prepare compounds with larger alkyl groups bonded to the Oxygen as well.

Therefore, one of ordinary skill in the art would be motivated to produce the instantly claimed compounds with the prior art disclosure.

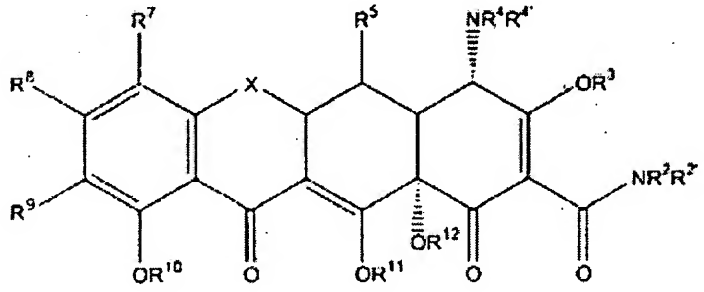
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-8, 11-13, 16, 19, 21 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Hlauka et al., US Pat. No. 5,494,903.

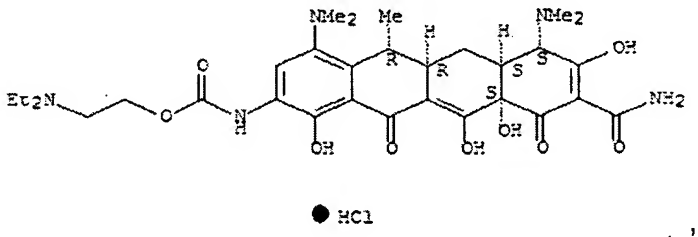
The instant application claims a compound of formula (I),



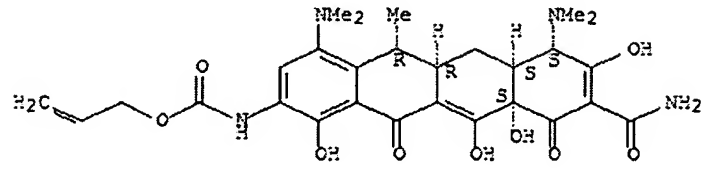
, wherein X is $CR'R^6$; R^2, $R^{2'}$, R^3, R^6, R^8, R^{9c}, R^{10}, R^{11} and R^{12} are each H; R^4, $R^{4'}$, and $R^{6'}$ are alkyl; R^9 is $NR^{9c}C(=Z')ZR^{9a}$; Z is O; Z' is O; and R^{9a} is substituted alkyl; and pharmaceutically acceptable salts thereof.

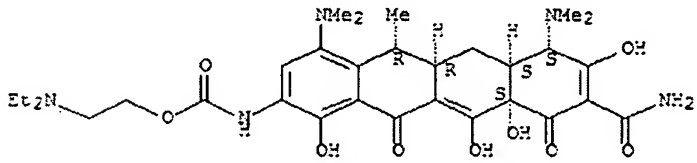
The instant claims were amended to change R^{9a} from "ethyl" to "substituted alkyl." Claim 1 does not state what the substituent on the alkyl group is. According to the specification, examples of possible substituents are alkyl, alkenyl, aminoalkyl, etc. (see p. 6, line 23 – p. 7, line 10). Thus, in the simplest case, the alkyl group can be substituted with an alkyl group, alkenyl group or an aminoalkyl group.

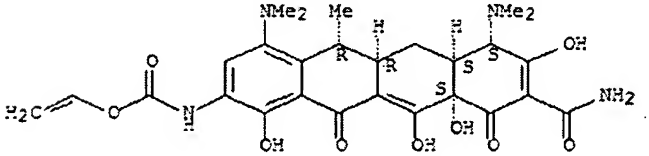
Hlauka et al. disclose the compounds and pharmaceutical compositions

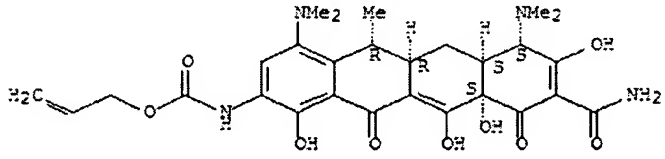


comprising the compounds:









and (see Hlauka et al., STN International (2005), HCAPLUS Database, Accession No. 1993:603237, Reg. Nos. 150231-22-4, 150231-23-5, 150251-76-6, and 150251-77-7).

Claim Rejections - 35 USC § 112

(Pending Rejections) Claims 1, 5, 9, 19, 27-28, 63 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As a result of the amendment filed 8/25/2006, the rejections were overcome and are now withdrawn.

(New Rejections) Claims 1-4, 6-14, 16, 19, 21, 23-26, 28-40, 56-68, 82 and 103-139 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, R^{9a} is "substituted" alkyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, etc. According the specification, examples of possible substituents include alkyl, alkenyl, halogen, hydroxyl, alkoxy, alkylcarbonyloxy, etc. (see p. 6, line 23 – p. 7, line 10). Although the specification provides for examples of possible substituents, there is no way to determine the meets and bounds of the claim. Moreover, in order to overcome the obviousness rejection above, the substitution limitations must be present. In order to overcome this rejection, the specific alternative substituents must be provided in the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds of the formula (I), wherein R^{9a} is substituted alkyl, alkynyl alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, arylsulfonyl, alkoxycarbonyl, arylcarbonyl, alkylamino, arylalkyl, aryl, heterocyclic, heteroaromatic, absent, or a prodrug moiety, the specification does not reasonably provide enablement of compounds of formula (I), wherein R^{9a} is **a steroid**.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation.

The factors include:

1) the nature of the invention;
2) the state of the prior art
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the breadth of the claims;
7) the quantity of experimentation necessary; and ,
8) the level of skill in the art.

The Nature of the Invention

The nature of the invention is a compound of formula (I) or a pharmaceutically acceptable salt thereof.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that a steroid is any of numerous naturally occurring or synthetic fat-soluble organic compounds having as a basis 17 carbon atoms arranged in four rings and including the sterols and bile acids, adrenal and sex hormones, certain natural drugs such as digitalis compounds, and the precursors of certain vitamins (see Abstract of American Heritage Dictionary, 4th Ed. (2000) on Dictionary.com).

The amount of direction or guidance presented and the presence or absence of working examples

The only direction or guidance present in the instant specification is for the compounds of formula (I) and pharmaceutically acceptable salts. The specification discloses the process of preparing over 100 different compounds of claim 1 (see Spec., p. 10-12). However, the specification provides no guidance and does not disclose a single species wherein R^{9a} is a steroid. The only guidance regarding a steroid is in the definition of a multicyclic moieity, which states that it can be a steroid, such as cholesterol (p. 23, line 26).

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure. Specifically, the instant claims are drawn to a compound of formula (I), wherein R^{9a} is a steroid.

The quantity of experimentation necessary

While the level of the skill in the pharmaceutical arts is high, it would require undue experimentation of one of ordinary skill in the art to prepare a compound of formula (I), wherein R9a is a steroid. The only guidance provided in the specification is for the compounds of formula (I) and pharmaceutically acceptable salts. There is no guidance or working examples present for compounds of formula (I) wherein R^{9a} is a steroid.

Therefore, the claims lack enablement. Deleting the words "a steroid" from the claim 1 and canceling claims 28 and 29 can overcome this rejection.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Andrew B. Freistein
Patent Examiner, AU 1626

for Joseph K. McKane
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